

corresponding to SEQ ID NO:10 and SEQ ID NO:11). The PCR products were resolved on a 4% agarose gel and stained with ethidium bromide.

As shown in Figure 5A, *H. pylori* nucleic acid was detected in the pre-treatment sample of the first patient (lane 3) and in all three pre-treatment samples of the second patient (lanes 7-9). After treatment began, less *H. pylori* nucleic acid was detectable (see treatment day 4 of the first patient (lane 4) and treatment day 7 of the second patient (lane 10)) until *H. pylori* nucleic acid was no longer detectable (see treatment days 10 and 14 of the first patient (lanes 5 and 6) and days 12, 13 and 18 and the post-treatment sample from the second patient (lanes 11-14)). In contrast, as shown in the corresponding lanes of Figure 5B, human nucleic acid was detected in each of the samples.

What is claimed is:

1    1.    A method for detecting a *Helicobacter pylori* infection, the method comprising  
2    the steps of:

3                 determining an integrity of a *Helicobacter pylori* nucleic acid present in  
4                 a patient sample; and

5                 identifying the patient as having a current *Helicobacter pylori* infection  
6                 if the integrity of the nucleic acid exceeds a predetermined threshold.

1    2.    The method of claim 1, wherein the identifying step comprises:

2                 comparing the integrity of the *Helicobacter pylori* nucleic acid to an  
3                 integrity of a non-*Helicobacter pylori* nucleic acid.

1    3.    The method of claim 2, wherein the non-*Helicobacter pylori* nucleic acid is a  
2    patient nucleic acid.

1    4.    The method of claim 2, wherein the non-*Helicobacter pylori* nucleic acid is an  
2    *Escherichia coli* nucleic acid.

1    5.    The method of claim 1, wherein the patient sample is selected from the group  
2    consisting of stool, sputum, pancreatic fluid, bile, lymph, blood, urine, saliva, gastric  
3    juice, and vomitus.

1    6.    The method of claim 5, wherein the patient sample is stool.

1    7.    The method of claim 5, wherein the patient sample is saliva.

1    8.    The method of claim 5, wherein the *Helicobacter pylori* nucleic acid is a DNA.

1    9.    The method of claim 1, comprising the further step of adding an ion chelator  
2    to the patient sample such that the concentration of the ion chelator is at least 150  
3    mM, thereby to preserve the integrity of the *Helicobacter pylori* nucleic acid.

1    10.    A method for grading a *Helicobacter pylori* infection in a patient, the method  
2    comprising the steps of:

3                   determining an amount of high-integrity *Helicobacter pylori* nucleic acid  
4                   present in a patient sample;

5                   comparing said amount with at least two standards comprising high-  
6                   integrity *Helicobacter pylori* nucleic acid, each standard being indicative of a  
7                   different grade of *Helicobacter pylori* infection; and

8                   grading a *Helicobacter pylori* infection based on said comparing step.

1       11.   A method for grading a *Helicobacter pylori* infection in a patient, the method  
2                   comprising the steps of:

3                   detecting a high-integrity *Helicobacter pylori* nucleic acid and a non-  
4                   *Helicobacter pylori* nucleic acid in a patient sample;

5                   determining an amount of the high-integrity *Helicobacter pylori* nucleic  
6                   acid relative to the non-*Helicobacter pylori* nucleic acid in the patient sample;

7                   comparing said amount with at least two standards of high-integrity  
8                   *Helicobacter pylori* nucleic acid relative to non-*Helicobacter pylori* nucleic  
9                   acid, each standard being indicative of a particular grade of a *Helicobacter*  
10                  *pylori* infection; and

11                  grading a *Helicobacter pylori* infection based on said comparing step.

1       12.   A method for monitoring progression of a *Helicobacter pylori* infection in a  
2                   patient, the method comprising the steps of:

3                   determining a first amount of a *Helicobacter pylori* nucleic acid in a first  
4                   sample obtained from a patient;

5                   determining a second amount of a *Helicobacter pylori* nucleic acid in a  
6                   second sample obtained from the patient;

7                   comparing the first amount with the second amount; and

8                   classifying the infection as diminishing if the second amount is less  
9                   than the first amount.

1       13. The method of claim 12, wherein the second sample is obtained no more than  
2       thirty days after the first sample.

1       14. A method for evaluating a course of treatment for a *Helicobacter pylori*  
2       infection, the method comprising the steps of:

3               obtaining a sample from a patient during a course of treatment or no  
4               more than thirty days after the course of treatment;

5               amplifying a high-integrity *Helicobacter pylori* nucleic acid present in  
6               the sample; and

7               identifying the patient as having a current *Helicobacter pylori* infection  
8               if the high-integrity *Helicobacter pylori* nucleic acid is present in the sample.

1       15. A method for evaluating the efficacy of a proposed treatment regimen for a  
2       *Helicobacter pylori* infection, the method comprising the steps of:

3               obtaining, from test patients diagnosed with an *Helicobacter pylori*  
4               infection, a test set of samples during the course of a proposed treatment  
5               regimen or no more than thirty days after the course of the proposed  
6               treatment regimen;

7               obtaining, from control patients diagnosed with an *Helicobacter pylori*  
8               infection, a control set of samples during the course of a control treatment  
9               regimen or no more than thirty days after the course of the control treatment  
10              regimen;

11              amplifying a high-integrity *Helicobacter pylori* nucleic acid present in  
12              the samples; and

13              comparing the amount of high-integrity *Helicobacter pylori* nucleic acid  
14              present in the test set of samples to the amount of high-integrity *Helicobacter*  
15              *pylori* nucleic acid present in the control set of samples.

1       16. A method for diagnosing a gastric disease in a patient, the method comprising  
2       the steps of:

3                   detecting a high-integrity *Helicobacter pylori* nucleic acid in a patient  
4                   sample; and

5                   identifying the patient as having a gastric disease caused by a  
6                   *Helicobacter pylori* infection if the high-integrity *Helicobacter pylori* nucleic  
7                   acid is present in the sample.

1       17. A method for detecting a *Helicobacter pylori* infection in a patient, the method  
2                   comprising the steps of:

3                   amplifying, from a patient sample,

4                   a first *Helicobacter pylori* nucleic acid at least 200 nucleotides in  
5                   length,

6                   a second *Helicobacter pylori* nucleic acid at least 400  
7                   nucleotides in length, and

8                   a third *Helicobacter pylori* nucleic acid at least 600 nucleotides  
9                   in length;

10                  detecting the amplified first, second, and third *Helicobacter pylori*  
11                  nucleic acids; and

12                  identifying the patient as having a *Helicobacter pylori* infection if the  
13                  amplified first, second, and third *Helicobacter pylori* nucleic acids are  
14                  detected.

1       18. A method for detecting a *Helicobacter pylori* infection in a patient, the method  
2                   comprising the steps of:

3                   determining the integrity of patient nucleic acids in a patient sample  
4                   comprising shed cells or cellular debris; and

5                   identifying the patient as having disease if the integrity of the patient  
6                   nucleic acids exceeds a predetermined threshold.